510(k) SUMMARY (per CFR21 807.92(c))

K062337

OCT - 5 2006

DEVICE DESCRIPTION:

Predicate Devices:

Aesculap USA: Modular Monopolar Electrodes	K970541
ACMI Circon: Surgical Instrument for Minimally Invasive Surgery	K914883

INTENDED USE:

Laparoscopic Electrodes and Handle are used to grasp, hold, coagulate, and cut tissue during laparoscopic surgical procedures

DEVICE COMPONENTS AND OPERATION:

Laparoscopic electrodes and handles are surgical instruments with interchangeable tip inserts designed to be introduced through a 5.5mm diameter (or larger) cannula, during laparoscopic surgical procedures. The devices can be used with electrosurgical generators. The interchange ability of the tip inserts allows for three main benefits:

- A removable insert allows for easier cleaning and disinfection of the instrument components,
- Versatility of the instrument is greatly increased as one handle can accept many tip configurations,
- Semi-disposability allows for multiple uses of one tip insert with cost effective replacement when worn or damaged.

The device consists of two components: an insulated, reusable handle and a series of reusable tips. Radiofrequency energy is passed to the tip through the handle and shaft by using a powered lead from an electrosurgical generator to a connector port on the handle. The insulated handle is the device that will be used by the physician or nurse to attach the tip and control the action of the tip via the grip. A rotary knob allows the tip to be positioned (rotated) while in the cannula.

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These devices use technology substantially equivalent to the Aesculap USA Modular Monopolar Electrodes (K970541) and the ACMI Circon Surgical Instrument for Minimally Invasive Surgery (K914883). Each consists of handles and a series of electrodes that are used to cut and coagulate tissue through the utilization of high frequency radiofrequency energy.

Laparoscopic electrodes are reusable and are resterilized using steam sterilization.

Aaron Laparoscopic Electrodes and Handle conform to the requirements of safety standard ANSI/AAMI HF-18 Electrosurgical Devices.

There are no significant differences in technology, performance, or intended use between the Aaron Laparoscopic Electrodes and Handle and the given predicate devices. There are no new questions raised regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2006

Aaron Medical
% Mr. Richard A. Kozloff
Vice President, Quality Assurance
Regulatory Affairs
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K062337
Trade/Device Name: Laparoscopic Electrodes and Handle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 9, 2006
Received: August 10, 2006

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062337

Device Name: Laparoscopic Electrodes and Handle

Indications for Use:

Laparoscopic Electrodes and Handle are used to grasp, hold, coagulate, and cut tissue during laparoscopic surgical procedures

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062337